UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM	Judge Patti B. Saris

MEMORANDUM OF WARRICK PHARMACEUTICALS CORPORATION IN SUPPORT OF THE MOTION TO DISMISS

Warrick Pharmaceuticals Corporation ("Warrick") moves to dismiss the State of Montana's Second Amended Complaint ("Mont. Cmplt.") and the State of Nevada's Amended Complaint ("Nev. Cmplt.") pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). Warrick manufactures only multi-source drugs, and "multi-source drugs do not fit the paradigm described in the complaint," as this Court explained in its May 13 Order in this multidistrict litigation. *In re Pharma. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 194 & n.11 (D. Mass. 2003). Montana and Nevada fail to fit the generic market into the paradigm of fraudulent conduct alleged throughout their Amended Complaints. All claims against Warrick should be dismissed for this reason alone. In addition, Montana and Nevada have failed entirely to satisfy the pleading requirements of Fed. R. Civ. P. 9(b) with respect to their allegations that Warrick failed to report its Best Price and offered allegedly "impermissible inducements" to providers. For these reasons, as well as those stated in the Consolidated Memorandum in Support of Defendants' Motion to Dismiss the

State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint ("Joint Memorandum"), all of the claims against Warrick must be dismissed.

ARGUMENT

I. The Amended Complaints Fail To State a Claim With Respect to Multi-Source Generic Drugs.

For the same reasons that this Court dismissed the claims against multiple-source generic drugs in its May 13 Order, all claims relating to multi-source generic drugs should be dismissed. *See In re Pharma. Indus. AWP Litig.*, 263 F. Supp. 2d at 194 & n.11. As to Montana's and Nevada's claims on behalf of Medicare beneficiaries, the States admit that the reimbursement for multi-source drugs is based on "the median AWP of all the generic forms of the drug or biological, or the lowest AWP of the brand name product." 42 C.F.R. § 405.517. Mont. Cmplt. ¶ 187; Nev. Cmplt. ¶ 150. Under the States' Medicaid Programs, reimbursement for multiple-source drugs for which there are at least three suppliers is equal to a specified dispensing fee plus "an amount equal to 150 percent of the lowest AWP published by First DataBank, Medi-Span or the *Red Book*." Mont. Cmplt. ¶ 188; Nev. Cmplt. ¶ 151. No manufacturer can obtain a competitive advantage or market share based on its own published AWP in a reimbursement scheme based on the median AWP or lowest published AWP.

The States' attempt to obscure this fundamental inconsistency by alleging – in the most abstract terms possible – that that "drug makers act in unison by elevating the AWP for all generic drugs," Mont. Cmplt. ¶ 189; Nev. Cmplt. ¶ 152, fails to allege any facts "with enough specificity to inform multiple defendants of facts forming the basis of the conspiracy charge." *Van Schaick v. Church of Scientology of Cal., Inc.*, 535 F. Supp. 1125, 1141 (D. Mass. 1982). Consequently, the Medicare and Medicaid AWP claims relating to multi-source drugs must be

dismissed. *See Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996); *Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985); *Herring v. Vadala*, 670 F. Supp. 1082, 1087 (D. Mass. 1987).

The States' allegations relating to reimbursement of multiple-source drugs in the "private payor arena" are similarly vacuous. As the States acknowledge, reimbursement for multi-source drugs is only "sometimes" connected to AWP at all, Mont. Cmplt. ¶ 194; Nev. Cmplt. 157, and at other times is based on a different benchmark entirely, the "maximum allowable cost" or "MAC." Mont. Cmplt. ¶ 193; Nev. Cmplt. 156. The States do not say which benchmark applies to albuterol. In short, the States have not identified with specificity a single Warrick drug whose reimbursement by a private payor was based on the published AWPs reproduced in their Amended Complaints. This failure to set forth a single meaningful allegation should not be excused, and all claims against Warrick should be dismissed.

II. All AWP-Based Claims Relating to Warrick Should Be Dismissed for Failure to Meet the Pleading Requirements of Fed. R. Civ. P. 9(b).

Independent of the fatal flaws inherent in the States' multi-source theory, they have failed to meet the pleading requirements imposed by Fed. R. Civ. P. 9(b) and this Court's May 13 Order. In particular, the Court required that in this multidistrict litigation, plaintiffs state "the allegedly fraudulent AWP for each drug." *In re Pharma. Indus. AWP Litig.*, 263 F. Supp. 2d at 194. Montana and Nevada have failed to allege a "fraudulent AWP" for any of the Warrick drugs identified in the Amended Complaints. The States cannot meet their burden of alleging a "fraudulent AWP" by simply identifying the published AWP without any explanation of how it is fraudulent or that it should have been lower. All claims against Warrick should be dismissed for these independent reasons. *See, e.g., Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997).

The States attempt to provide some content to the notion of a "fraudulent AWP" for Warrick's drugs by reference to an alleged "spread," but fail to set forth in any meaningful or

consistent way the price points defining the "spread." Their suggestion that the top point of the "spread" is defined by reference to the published AWP simply makes no sense. Neither Montana nor Nevada alleges that it believed that the published AWPs represented prices that were actually paid by anyone, or that they did not know that drugs – like all commodities that consumers buy indirectly – are priced differently at different points along the distribution chain.[1] Nor, in two 100+ page complaints alleging pricing fraud, has either State alleged the price it actually paid for a single drug, and they offer no explanation for their failure to do so. *Compare Efron v. Embassy Suites (Puerto Rico), Inc.*, 223 F.3d 12, 16 (1st Cir. 2000) (explaining that relaxation of pleading requirements where information in defendants sole possession does not apply where the information is held by plaintiffs), *cert. denied*, 535 U.S. 905 (2001). *See also Tapogna v. Egan*, 141 F.R.D. 370, 373 (D. Mass. 1992) (dismissing amended complaint with prejudice because plaintiffs had "ample opportunity" to allege fraud with particularity).

In the few instances where Montana and Nevada even attempt to state the price defining the bottom of the "spread," their allegations are not sufficient. The scant additional information that is provided in the Amended Complaints suggests vague, contrary theories about what that bottom price point might be. The States refer alternatively to various prices, including "invoice cost," the "invoice price," the "net price (after rebate)," "Minimum GPO Price Guide," and the "Target GPO Price Guide," without specifying what these price points mean or which of them – if any – is relevant to their theory or makes the published AWP "fraudulent." Mont. Cmplt. ¶ 540; Nev. Cmplt. ¶ 341. Montana and Nevada cannot adequately plead a "fraudulent AWP" by simply identifying any price in the distribution chain that any entity happened to pay for a drug without pleading facts which, if proved, would constitute a fraud with respect to the associated

[1] Indeed, as explained in detail in the Joint Memorandum, Montana and Nevada have long been well aware that many AWPs represented a list "sticker" price well above provider acquisition cost.

Warrick drug. In short, the States have not explained how or why any published AWP is fraudulent, and to the extent they intend for allegations about the "spread" to fill that gap, they have not adequately defined that term so that their theory of the case can be divined. Consequently, all claims against Warrick should be dismissed in their entirety under Rule 9(b).

III. **The States' Allegations Concerning Best Price Reporting and Utilization of "Impermissible Inducements" Must Be Dismissed under Fed. R. Civ. P. 9(b).**

Finally, the broad, general allegations that the defendants "did not report the actual Best Price or AMP" and "utilized other impermissible inducements to stimulate the sales of its drugs" are wholly without substance and should be dismissed in their entirety. Mont. Cmplt. ¶¶ 542, 612; Nev. Cmplt. ¶¶ 343, 392. Both States fail to provide a *single specific example* of a failure by Warrick to report its statutory Best Price or AMP to CMS, or of any "impermissible inducements" allegedly offered by Warrick to providers. These claims fail to state the requisite "who, what, where and how" of Warrick's alleged fraud, *see United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001), and are insufficient under Rule 9(b) to "place [Warrick] on notice and enable [it] to prepare meaningful responses." *New England Data Servs. v. Becher*, 829 F.2d 286, 289 (1st Cir. 1987).[2]

CONCLUSION

For the foregoing reasons, as well as those stated in the Joint Memorandum, Warrick requests that Montana's Second Amended Complaint and Nevada's Amended Complaint be dismissed, and that the dismissal be with prejudice.

[2] Warrick also hereby adopts the argument of Abbott Laboratories, Inc. ("Abbott") in Abbott's Separate Memorandum of Law in Support of its Motion to Dismiss Montana's Second Amended Complaint for all of Warrick's non-innovator multiple-source drugs, such as griseofulvin ultramicrocrystalline and oxaprozin. On the basis set forth therein, Warrick urges that the Court dismiss all Medicaid rebate claims against non-innovator multiple-source drugs.

Respectfully Submitted,

Original Signature On File With Court

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Dated: September 15, 2003

CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2003, I caused a true and correct copy of the Memorandum of Warrick Pharmaceuticals Corporation in Support of its Motion to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

John R. Therien